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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/540,623 | 07/25/2005 | Yasuhiro Kajihara | TAM-055 | 7139 |

20374 7590 11/17/2006

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EXAMINER

HENRY, MICHAEL C

ART UNIT PAPER NUMBER

1623

DATE MAILED: 11/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/540,623 | Applicant(s) KAJIHARA ET AL. | |
| | Examiner Michael C. Henry | Art Unit 1623 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3, 6-9, 11 and 12 is/are allowed.
- 6) ☒ Claim(s) 4, 5 and 10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>6/24/05 & 2/7/06</u> . | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Claims 1-12 are pending in application

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement filed complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is indefinite since it recites removing asparagine moiety and because it unclear how the asparagines moiety can be removed without removing the lipophilic protective group, Q. Also, it is unclear whether or not the lipophilic protective group is attached after the removal of the asparagine moiety.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Endo et al. (The Journal of Biological Chemistry (1982) Vol. 257. No. 15, pages 8755-8760).

Claim 4 is a product-by-process claim wherein the applicant claims a 3-branched asparagine-linked oligosaccharide obtained by removing the lipophilic protective group, biotin group or FITC group from the 3-branched asparagine-linked oligosaccharide derivative of claim 1 or 2. Endo et al. disclose applicant's 3-branched asparagine-linked oligosaccharide devoid of a lipophilic protective group, biotin group or FITC group (see the triantennary glycan on page 8755). A quotation from the MPEP (Manual of Patent Examining Procedure, 8 ed., August 2001) pertaining to Product-by-Process Claims is given below in order for further corroborate the reason for the aforementioned rejection. The quotation states that "PRODUCT-BY-PROCESS CLAIMS ARE NOT LIMITED TO THE MANIPULATIONS OF THE RECITED STEPS, ONLY THE STRUCTURE IMPLIED BY THE STEPS "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)."

Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Barsomian et al. (US 5,238,821).

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In claim 10, applicant claims a process for preparing a 3-branched oligosaccharide characterized by removing asparagine moiety from a 3-branched asparagine-linked oligosaccharide. Barsomian et al. disclose applicant's process for preparing a 3-branched oligosaccharide characterized by removing (enzymatically) asparagine moiety from a 3-branched asparagine-linked oligosaccharide (see abstract and figure 1; see also col. 1, lines 41-56).

Allowable Subject Matter

The following is an examiner's statement of reasons for allowance: The examiner has found claims 1-3, 6-9, 11 and 12 to be unobvious over the prior art of record and therefore to be allowable over the prior art of record. The present invention relates to 3-branched asparagine-linked oligosaccharide derivative of a given formula (1) wherein the nitrogen of amino group of asparagine is modified with a lipophilic protective group, biotin group or FITC group. The Furthermore, the invention relates to a method of preparing said 3-branched asparagine-linked oligosaccharide derivative. The very relevant prior art document Endo et al. (The Journal of Biological Chemistry (1982) Vol. 257. No. 15, pages 8755-8760) to this invention does not disclose or suggest the 3-branched asparagine-linked oligosaccharide derivative not the method of preparing the same.

Conclusion

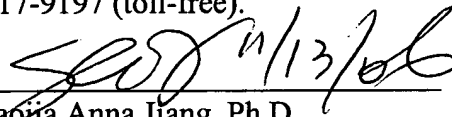
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be

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reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry


Shaojia Anna Jiang, Ph.D.
Supervisory Patent Examiner
Art Unit 1623

November 9, 2006.